INSTRUCTIONS FOR COMPLETING AN APPLICATION FOR LICENSURE OF A

CLINICAL LABORATORY- CLIS FORM CL-3—September 2006

When completing your license application, please pay particular attention to the following:

1) Licensure fees (page B)

2) The clinical laboratory licensure unit is now using a unique CLIS ID number, which is located on the top right hand corner of your license, for all your records. Please include this number on all renewal applications and any correspondence to the department.

3) Enrollment in proficiency testing – Please indicate, in the upper right corner at page 1, your proficiency testing provider(s), e.g., CAP, AAB and/or NJ.

4) Normal hours of operation (page 1): This pertains to laboratory-associated activities only, i.e., the collection and/or testing of patient specimens and reporting of test results. It does not pertain to the normal business hours of the facility in which the laboratory is located.

5) Ownership section (page 2): You must include anyone owning 5% or more having direct or indirect ownership interests or controlling interest, and define the corporate structure.

6) Information on the laboratory director (page 3) and the co-director (page 4): **List home address of director/co-director not laboratory address**, specific days and hours on the premises at the applicant site and any other testing site(s) within and outside of New Jersey must be included.

7) General Supervisor vs. Technical Supervisor (page 5): **A qualified General Supervisor must be on the laboratory premises during all regularly scheduled hours in which tests are performed.** A Technical Supervisor spends an adequate amount of time in the laboratory supervising the technical performance of the staff and is readily available for consultation. This position has a minimum education requirement of a master's degree for some specialties/subspecialties.

8) Laboratory specialties/subspecialties (pages 8 and 9): Include all specialties and subspecialties in which you are requesting licensure renewal.

9) Laboratory workload data (pages 8 and 9): The annual numbers of tests or specimens must be entered. Refer to enclosed "Guidelines for Counting Tests for CLIS-Laboratory Workload Data." **On page 9, in addition to listing the**

annual total number of patients accessioned, list the annual test volume for your laboratory on the right side of that box.

10) The information requested on page 11 has been added to the application since 2003.
Level 1 – this level is acceptable for handling agents not known to cause disease in healthy adults.
Level 2 – level 2 is appropriate when tests are performed on human derived blood, body fluids or tissues where an unknown infectious agent may be present.
Level 3 – this level is applicable to clinical facilities that work with infectious agents with a potential for respiratory transmission.
Level 4 – laboratory practices, safety equipment and facilities are applicable to working with dangerous and exotic agents which pose a high risk for life threatening disease for which there is no available vaccine or therapy.

11) Equipment (page 14). **List all current equipment in use for 2007. Do not rely on what was submitted in prior applications. Include serial numbers.**

12) Laboratory charges (page 15): Submit a list of all tests performed and all current fee schedules (CD or disk is acceptable and preferred) with your application.

13) Signatures and notarization (page 15): **The application must be signed by the director, co-director, and owners.** Notarization is no longer required for renewal applications. Initial CLIS license applications must still be notarized.

Collection Stations
Complete a separate application using pages 1 and 15 only for each collection station site.

Test Expansion/Prelicensure
Licensure in a specialty does not allow you to add tests or subspecialties under that specialty without approval from CLIS. For example, licensure in Toxicology for therapeutic drug monitoring does not permit you to perform testing for drugs of abuse. If you intend to offer an additional test or examination in 2007, a written request, signed by the laboratory director, must be submitted for the addition. You must demonstrate that you have successfully participated in an approved proficiency-testing program for at least one event (minimum four challenges), before we will approve it for patient testing and add it to your license. If an approved proficiency-testing program is not available, acceptable documentation of validation must be submitted with your expansion request.

Please use the new Prelicensure/Expansion application form (CL-2) available on our website for requesting test expansion or initial prelicensure testing.

Notification of Changes
You are reminded that under the provisions of N.J.S.A. 45:9-42.32, you must notify the Clinical Laboratory Improvement Services (CLIS) within 14 calendar days when a change in ownership or directorship occurs. A laboratory that changes ownership is required to re-apply for licensure that includes submitting the completed form CL-3

Application for a State Clinical Laboratory License, fees and CMS 1513 -Disclosure of Ownership and Control Interest Statement or state CL-9 form. Instructions for completing the ownership forms can be found in the federal CMS-1513 form. These forms are located on our website.

You must also notify CLIS when there are changes in the operation of the laboratory such as termination of services, address, hours of operation, supervisory personnel and any additions or deletions to your testing menu. Any changes must be submitted in writing and signed by the laboratory director.

Out-of-State Laboratories

Please note that laboratories located outside the state of New Jersey will be required to obtain a clinical laboratory license for 2007 only if that out-of-state laboratory has a collection station in the state of New Jersey or is directly involved in the collection or transport of specimens from New Jersey facilities to the out-of-state laboratory. N.J.S.A. 45:9-42.27.a. defines a collection station as "any facility used for the collection, processing and transmission of specimens to another facility for the performance of clinical tests."

Written Correspondence

Please address all correspondence to the attention of Joan Mikita, CLIS Licensing Supervisor, at the addresses below.
License renewals and proficiency testing enrollment forms shall be submitted together for 2007 and shall be mailed to:

Regular Mail
Joan Mikita, Licensing Unit- Rm 405
Clinical Laboratory Improvement Service
New Jersey Department of Health and Senior Services
PO Box 361
Trenton, NJ 08625

Next day or 2nd Day Air
Joan Mikita, Licensing Unit, Rm. 405
Clinical Laboratory Improvement Service
New Jersey Department of Health and Senior Services
John Fitch Plaza H & A Bldg.
369 South Warren Street at Market
Trenton, NJ 08608

If you have any questions or require assistance, you may contact the Licensing and Regulation Compliance unit at 609-292-4585 or 609-984-7923.

Joan Mikita, M.S., Supervisor
Licensing and Regulatory Compliance
Clinical Laboratory Improvement Service